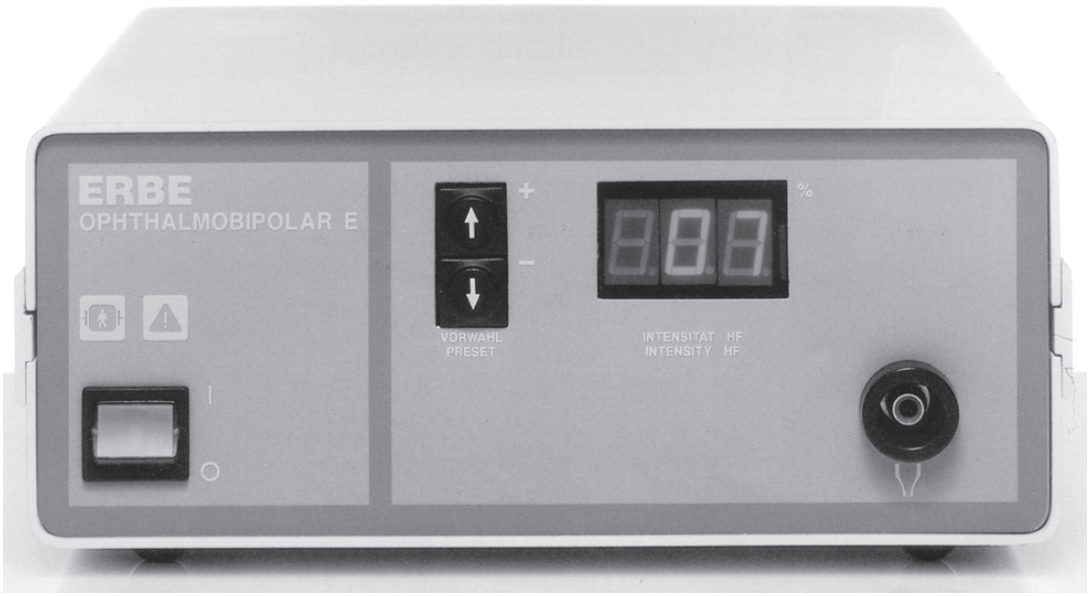
Ophthalmobipolar E

User Manual



11.1998

ERBE

OPHTHALMOBIPOLAR E

User Manual

ISO 9001
EN 46001

CE 0124

Instruction manual no. 80172-001
Ophthalmobipolar E no. 10739-002

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Contents

CHAPTER 1

Intended use, Technical Data, Meaning of the safety instructions

Intended use

The *Ophthalmobipolar E* is of modular design and affords:

- high-frequency bipolar coagulation current for the coagulation of intraocular hemorrhages and for coagulation preparatory to sclerotomy;
- high-frequency bipolar coagulation current for coagulating vessels.

Technical Data

The rating plate fixed at the bottom of the instrument lists the most important information of the *Ophthalmobipolar E*. Besides pertinent technical data, the necessary type and serialnumbers are recorded here. In the event of claims, servicing requirements, etc. always state the type number and serial number specified on the rating plate.

The Safety instructions mean:

WARNING 

The safety instruction WARNING denotes a danger which can cause damage to persons.

CAUTION 

The safety instruction CAUTION denotes a danger which can cause damage to property.

ATTENTION

The safety instruction ATTENTION denotes a danger which can cause failure of the device.

CHAPTER 2

Inspection on Delivery and Installation of the Unit

Inspection on Delivery

On delivery, instruments should be checked immediately for damage caused in transit, and subjected to a performance test.

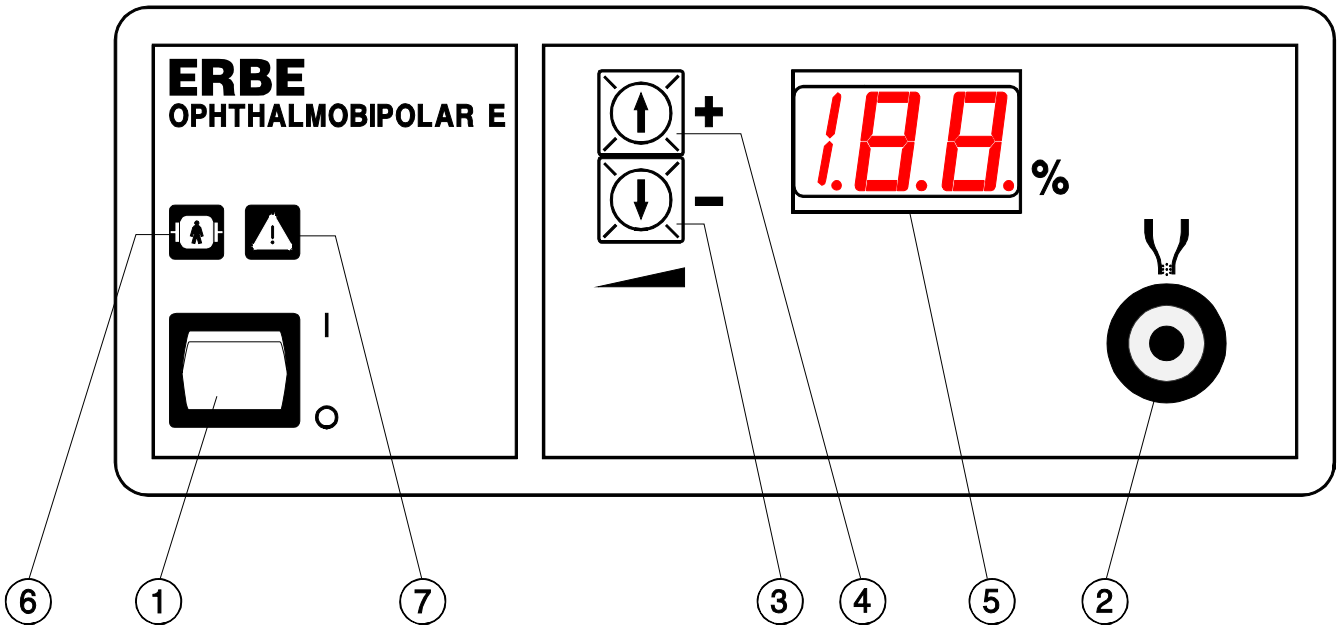
In the event that an instrument has suffered damage in transit, a complaint should be lodged at once with the carrier, and a certificate of damage should be prepared to secure the recipient´s rights of recovery, the certificate should contain the date of delivery, the type and serial numbers of the instrument delivered, and a description of the damage.

The original packaging should be kept till the end of the warranty period, so that, if necessary, the instrument can be returned in it.

Installation

The instructions pertaining to installation in Chapters 6 (Precautions against fire and explosion) and 7 (Precautions against damage of the unit) must be followed.

The*Ophthalmobipolar E* ophthalmosurgical unit must be connected to a properly installed shock-proof socket by means of mains cable supplied by the manufacturer or of the same quality as those supplied by the manufacturer. For safety´s sake, multiple sockets and extension cords should not be used if at all possible. When their use cannot be avoided, these too should have proper earthing contacts.



(1) Mains switch

(2) Socket for Bipolar Coagulation Electrodes and Forceps

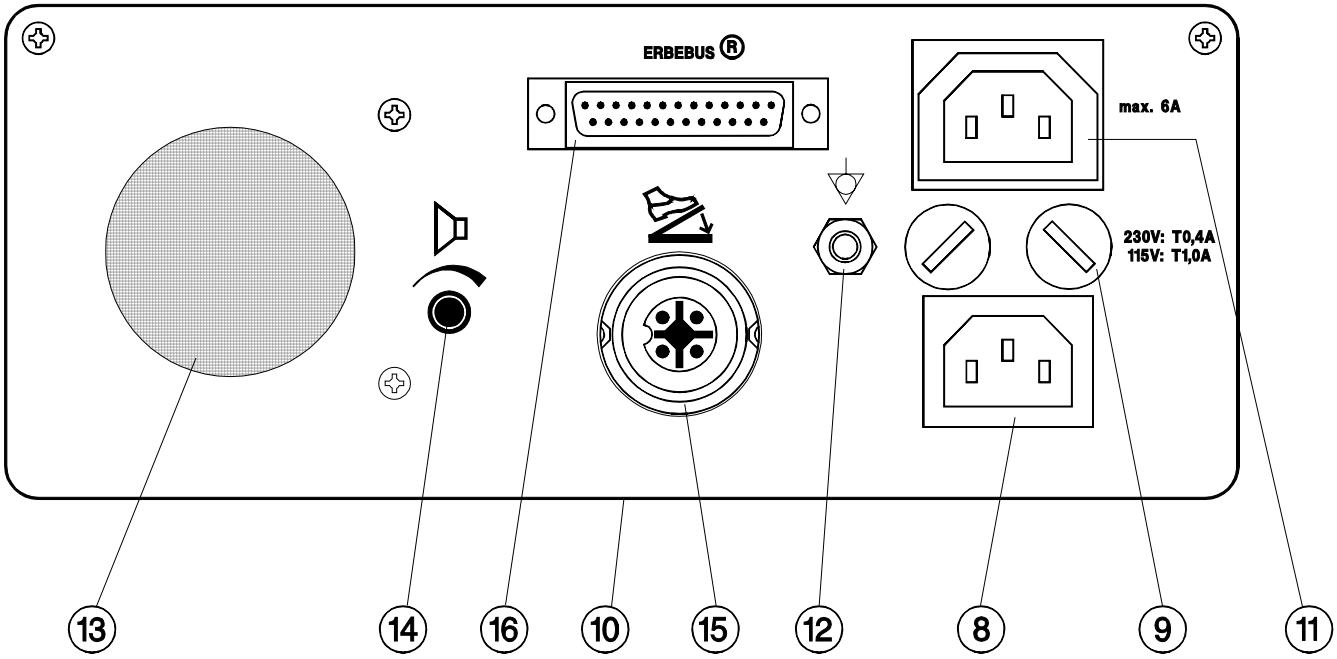
(3) Output Preset - (less)

(4) Output Preset - (more)

(5) Output Display

(6) IEC Symbol, type BF

(7) Symbol for "Danger, see Accompanying Documents"



(8) Electric Mains Connection

(9) Mains Safety Fuses

(10) Name Plate (on the bottom of the unit)

(11) Mains Outlet

(12) Mains Outlet

(13) Loudspeaker

(14) Volume Control

(15) Pedal Switch Socket

(16) ERBEBUS Interface

CHAPTER 3

Operating Elements

(1) Mains Switch

The *Ophthalmobipolar E* is operative as soon as the mains switch is actuated. The green lamp in the mains switch signals that the device is operative. Should the signal lamp go out after actuation of the mains switch, either there is no power or the mains fuse is defective.

(2) Socket for bipolar Coagulation Forceps and Electrodes

Hier können sowohl bipolare Pinzetten, Bipolarstifte, als auch intraokulare Elektroden angeschlossen werden.

(3 + 4) Output Preset Buttons

Display 5 reads "00" when the device is switched on. The output can be increased by pushing button 4. A too high a preset output can be reduced by pushing button 3. The intensity of the output is shown as a percentage of the maximum output.

(5) Output Display

This display continuously shows the value of the preset output.

(6) IEC Symbol "BF"

The *Ophthalmobipolar E* is a BF unit by the standards of IEC 601, Part 1. This means, that the patient can be defibrillated safely, and that the neutral electrode therefore can remain on patients during defibrillation.

(7) Symbol for "Danger, See Accompanying Documents"

The operating instructions must be read before initial operation.

(8) Mains Connection

The *Ophthalmobipolar E* ophthalmosurgical unit must be connected to a correctly installed grounded socket by means of a mains cable supplied by the manufacturer or comparable to those supplied by the manufacturer (i.e.bearing a national seal of approval). As a safety precaution, multiple sockets and extension cords should not be used if possible. If used, they should be properly earthed.

(9) Mains Safety fuses

The device is protected by two super-surge-proof fuses. In the event that either of these fails, an authorized technician should check the unit before it is put into service again.

(10) Type Plate

The type plate fixed to the bottom of the instrument lists the most important ratings of the *Ophthalmobipolar E*:

(11) Mains Outlet

Other ERBE instruments can be linked here to the *Ophthalmobipolar E* with a short cable.

WARNUNG 

This outlet is not protected by a fuse.

(12) Equipotential Boning Pin

The *Ophthalmobipolar E* can be connected to the ground terminal in the operating room by means of the earthng line supplied with each unit. The connection is marked with this symbol:

(13) Loudspeaker

Amplifies acoustic signals

(14) Volume Control

The *Ophthalmobipolar E* produces an acoustic signal during activation of the high-frequency generator: the volume of the signal is adjustable by a screw driver.

(15) Connection for Pedal Switch

A pedal switch is connected to this socket. High-frequency current for bipolar coagulation can be switched on with the pedal.

WARNING ⚠

Only explosion-proof pedal switches may be used in potentially explosive areas.

(16) ERBEBUS

The ERBEBUS is an interface system by means of which various instruments from the ERBE line can be linked with each other and - depending on combination and preset - operated with a single pedal switch.

CAUTION ⚠

Only Units of the ERBE System may be connected to the ERBEBUS

Units of the ERBE System are:

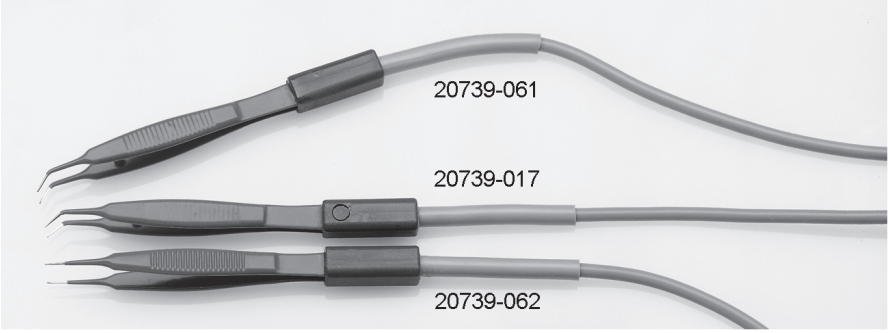
Aspimat E, Phakotom E, Vitrektom E, Erbokombi E, Ophthalmobipolar E, Ophthalmotom, Erbokryo AE, Diacapsutom

CHAPTER 4

Description of Accessories

Here the functions and characteristics of the most important accessories for high-frequency surgery with the *Ophthalmobipolar E* are described. For our entire line of accessories, see the latest ERBE brochures.

Bipolar Coagulation Forceps



Bipolar coagulation forceps are connected to the bipolar outlet (2) of the *Ophthalmobipolar E* and can be activated with the footswitch.

The wide range of uses of bipolar coagulation forceps both in dissection and in the coagulation of tissue necessitates a variety of types of forceps, all of which however are basically of the same design.

The blades of the forceps are insulated with a coating of electrically nonconductive plastic, to prevent inadvertent coagulations in the orbity.

Bipolar coagulation forceps can be connected to the *Ophthalmobipolar E* with a 3.0 m electrode cable.

The bipolar coagulation forceps and the cable can be autoclaved at temperatures of up 134 °C.

Bipolar Coagulation Probes

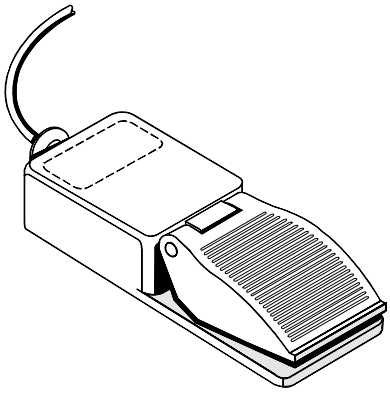
Bipolar endocoagulators, with or without an unfusion/aspiration connection, are available for intra-ocular coagulation in retonal hemorrhage.

Bipolar probes, with or without an infusion connection, are available for scleral coagulation preparatory to opening the anterior chamber. Bipolar rather than monopolar coagulation should be performed whenever possible.

Footswitch

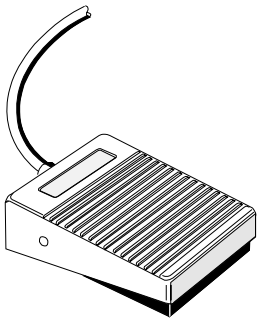
Either of two footswitches of ERBE can be used to activate high-frequency output.

Explosion-Proof Footswitch (20711-008)



This switch has a water- and explosion-proof metal housing.

Non-Explosion-Proof Footswitch (20711-009)



This pedal may be used only where there is no risk of explosion. The agents used to clean and disinfect the pedal switch must be nonflammable and non-explosive (e.g. soap suds)

CHAPTER 5

Performance Test

Before every use, the operability of the instrument should be checked as follows:

Mains switch

When an *Ophthalmobipolar E* ophthalmosurgical instrument is properly connected to an a.c. mains supply with the mains cable supplied with the instrument, the signal lamp in the mains switch should light up when the switch is on.

Output of the bipolar generator

To test the output of the bipolar generator, connect the bipolar forceps to the generator, and set the generator at maximum output.

When the bipoar high-frequency current is activated with the pedalswitch, an acoustic signal sounds.

Whether high-frequency current is present at the bipolar outlet can be checked with a wet sponge. If the generator is functioning properly, steam will be produced as soon as the tips of the bipolar forceps touch the sponge.

CHAPTER 6

Risks and Safety of High-Frequency Surgery

WARNING ⚠

General notes

1. Patients should be prevented from touching metal parts that are earthed or have an appreciable earth capacitance (operating table, mountings, etc.). The use of antistatic towels is recommended for this purpose.

2. Skin-with-skin contact (e.g. between a patient,s arms and trunk) should be avoided, e.g. by interposing dry gauze.

3. When simultaneously performing High Frequency Surgery, and using physiological monitoring devices on a patient, any monitoring electrode should be attached as far from the surgery electrodes as possible. Needle electrodes for monitoring are not recommended. The use of monitoring electrodes with HF-current-limiting provisions is recommended in all cases.

4. The leads to the surgery electrodes should be routed such that they touch neither the patient or other leads. Temporaly unused Active electrodes should be positioned such that they are not touching the patient.

5. Use of the bipolar technique is sometimes indicated for surgery on body parts with comparatively small cross-sections, to prevent inadvertent coagulation.

6. Output should be set at the lowest value sufficient for one´s purpose.

7. The use of flammable anesthetics, e.g. laughing gas (N_20), and oxygen should be avoided during surgery in the areas of the thorax and head, unless these gases can be pumped off or an instrument approved for use with anesthetics is to be used. Flammable cleaners, disinfectants, and solvents for adhesives should be allowed to evaporate prior to HF surgery. Flammable liquids are apt to collect under a patient or in bodily depressions or cavities (e.g. navel, vagina). Liquids that have collected in these places should be wiped up before a HF instrument is used. Surgeons are also warned of the risk of igniting endogenous gases. Such materials as cotton wadding and gauze, if saturated with oxygen, can be ignited by the sparks that occur even when HF surgical instrument is used correctly.

8. In patients with pacemakers or pacemaker electrodes there is a risk of a disturbance of pacemaker function or of the pacemakers being damaged. When in doubt, one should consult the cardiology department.

9. Use of a HF surgical unit is apt to interfere with other electromedical units.

10. The unit is equipped with elecronic sagety functions wich can be triggered by severe disturbances in the power supply and which can reset the unit to

stand-by operation with the intensity "00". Audible alarms can be issued as a result. After turning the power off briefly and back on again, the intensity can again be preset and the unit activated.

11. High-frequency surgical instruments always produce sparks on their active electrodes while in operation. For this reason one must be careful not to use flammable or explosive anesthetics, skin cleaners, oil removers, or disinfectants during high-frequency surgery. At all events, before a high-frequency surgical instrument is switched on, such agents should be removed from the area of the active electrode or allowed to evaporate entirely. The same holds for gauze bandages and dry triangular swabs.

Important notes on bipolar surgery

Bipolar surgery is expecially well suited for the thermal coagulation of blood vessels, i.e. for hemostasis. When it is performed for this purpose, the following complications can occur:

Adhesion

During a coagulation procedure the coagulum may stick more or less firmly to the tips of the bipolar forceps, so that, when the electrode is removed, the coagulum is detached, in part or in its entirety, from the surrounding tissue, and the blood vessel is reopened. Adhesion results primarily from the thermal conversion of collagen into glucose and the rapid dessication of the coagulum, which will contain a greater or less amount of glucose.

To prevent, or at least to minimize, adhesion, the HF current should be switched off as soon as there is a large enough coagulum, especially as there is no benefit to be gained from prolonging the duty cycle after coagulation has occurred. Further, one must take care that the bipolar forceps and eletrodes are always clean, i.e. that there are no remnants of tissue from revious coagulations clinging to the surfaces of the electrodes.

Adhesion is most apt to occur when even fairly dry tissue is coagulated. Before coagulation it is wise to moisten dry tissue with sterilized water or physiological saline. Blood that flows during hemostasis from the vessel that is to be coagulated is unsuited for this purpose, since it too will coagulate during the procedure. Should a forceps or electrode stick to the coagulum despite these precautions, it is better to switch off the current and wait a few seconds than to try tearing the forceps or elctrode free. Fluids from tissue surrounding the coagulum and the will flow through capillary action to the surfaces between the coagulum and the tips of the forceps and dissolve the adhesion. In a pinch a drop of sterile water or phsiological saline may help.

Burst Coagulum

If the high-frequency output is set too high during bipolar coagulation, the intensity of the HF current flowing between the tips of the bipolar forceps and through the coagulum will be so great as to cause a sudden sharp rise in the temperature of the tissue; vapour pressure will be generated which is strong enough to burst the coagulum as if by explosion. This undesirable effect is easily prevented by setting the HF-output correctly.

Absence of the Coagulation Effect

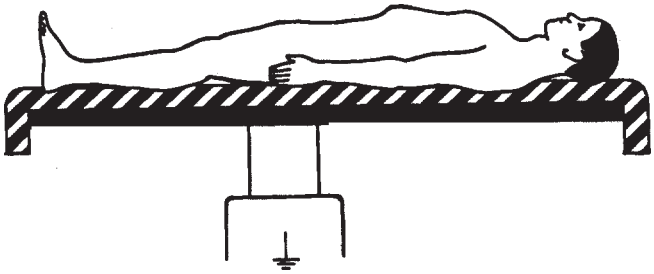
During coagulation the surface of a bipolar forceps is invariably moistened with body fluid. After the procedure, while the forceps are not being used, the body fluid dries on the surface of the forceps and leaves an electrically nonconductive film. If the forceps are used again before they have been

cleaned, the flow of HF current will be inadequate, especially if the tissue is dry. It is therefore advisable to wipe off bipolar forceps between coagulations with a sterile wet cloth. When one is done using them, bipolar forceps should be treated as described in the section on cleaning, disinfecting, and sterilizing accessories.

Please note:

During high-frequency surgery the patient must not come into contact with electrically conductive objects (the operating table, mountings, wet cloths, etc.)

A thick, dry, electrically nonconductive pad must be laid between the patient and the operating table and mountings. This pad must not become moist during high-frequency surgery.



Areas of the body that perspire freely, arms laid at the sides of the trunk, and skin in contact with skin should be insulated by interposing dry towels.

When injection cannulae are used as ECG electrodes the metal cones must not lie on the skin; the same applies to leads to monitoring instruments as well.

The leads to the bipolar high-frequency electrodes should be as short as possible and without loops, and should be laid so as not to touch the patient or other lines.

Only those lines which are intended by the manufacturer for use with the instrument may be used.

During high-frequency surgery sparking can occur on the active electrode, which can ignite flammalble or explosive materials.

Pacemaker

In patients with pacemaker or pacemaker-electrode implants, the use of high-frequency surgery is apt to cause irreparable damage to the implants and to effect their functioning, possible to the extent of causing ventricular fibrillation.

The monitoring of such patient with measuring instruments is recommended.

CHAPTER 7

Maintenance, Cleaning, Disinfection and Sterilization

Maintenance of the unit

Precautions Against Damage of the Instrument

Protecting the instrument effectvely from damage involves operating it properly and having it properly serviced, and setting the instrument up in a safe place. This means attaching the ophthalmosurgical instrument securely to its base, keeping moisture and dirt out of the instrument, and keeping it away from flammable and explosive materials. To ensure good radiation of heat produced by the instrument during operation, the circulation of air through the cooling vents must not be blocked.

Cleaning and Disinfection of the Instrument

The housing of the *Ophthalmobipolar E* should be cleaned only with nonflammable, non-explosive agents. Care should be taken not to allow moisture to enter the instrument.

Should one have no choice but to use a flammable or explosive agent, this agent must be completely evaporated before the instrument is switched on.

Maintenance of the accessories

Precautions Against Damage of the Accessories

To prevent premature wear of the accessories, the following steps are advised:

Always handle and store bipolar electrodes in such a way that they will not be damaged.

Store *bipolar coagulation forceps* in such a way that the tips will not be damaged. These forceps are best stored and transported in a special sterilization container.

Forceps with insulated blades should not be cleaned or stored with other hard or pointed instruments, as this may damage the insulation. Bending the blades of the forceps apart may cause the insulation to split.

Do not carry the *footswitch* by its cable. Do not wind the cable tightly around the footswitch.

Cable and Plug: Do not kink or fold the cable or wind it tightly. Never remove a plug from the *Ophthalmobipolar E* by tugging sharply on the cable; pull on the shaft of the plug.

Cleaning, Disinfecting, and Sterilizing of the Accessories

Bipolar Active Electrodes: Remnants of tissue and dried-on body fluids should not be scraped off electrodes with any hard, sharp object, such as a scalpel, scissors, or a knife. This could damage both the insulation and the contact surfaces of the electrodes. Dried-on tissue or body fluids usually can be softened in warm water and then easily wiped off with soft towels. If all else fails, tissue that is burned onto an active electrode should be removed, carefully, with fine metal wool. The electrodes can be sterilized by steam at temperatures of up to 134°C.

Footswitches: Because the risk of fire or explosion, footswitches that are not explosion-proof should be cleaned only with soap suds or other nonflammable agents.

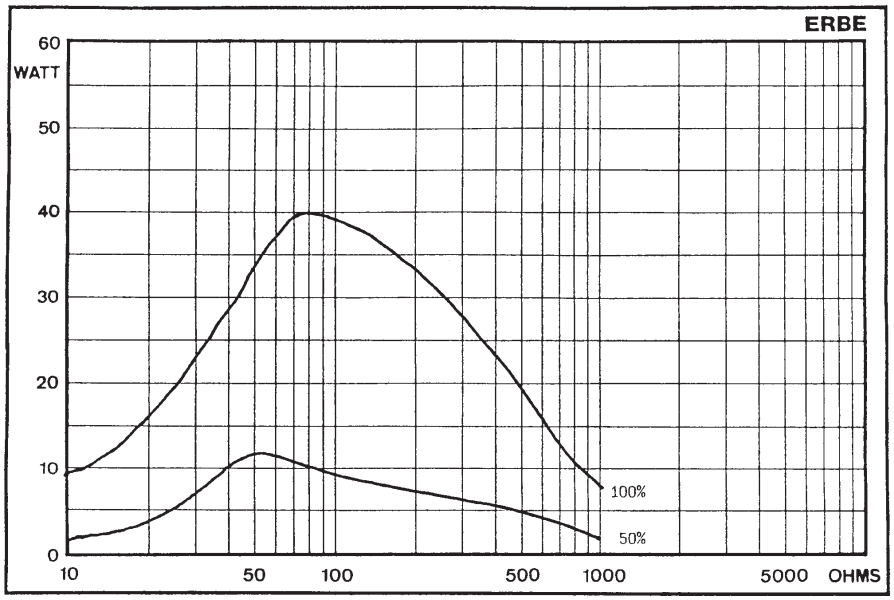
The surfaces of explosion-proof footswitches can be disinfected with ordinary disinfectants.

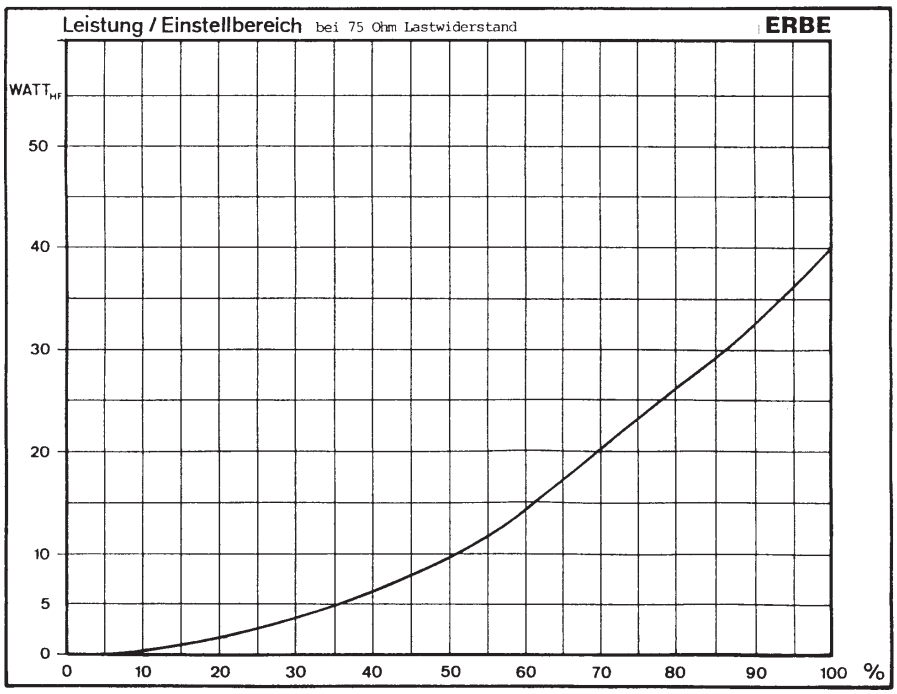
CHAPTER 8

Technical Data

Line Voltage and Frequency	230 V +/- 10 %, 50/60 Hz
Line Fuse	T 0,4 A
Class according to EN 60601-1	I
Output Type according to EN 60601-1	BF
Power Consumption	max. 90 W
LF Leakage Current	
- from ground	max. 0,5 mA
- from housing	max. 0,1 mA
- from bipolar output	max. 0,1 mA
Max. Spitzenausgangsspannung	160 Vp
HF-Output	40 W bei 75 Ohm
Rated Frequency	2,2 MHz
Output Adjustment	Continuously from 0 bis 100 %
Acoustic Signals	
HF Surgery	Continuous tone
On-Signal	Three tone sequence
Error	Modulated tone
Optical Signals	1 Signal Lamp
Activation of HF Output	By footswitch
Measurements	W x H x D = 230 x 100 x 330mm
Weight	6,0 kg
Aussetzbetrieb	10 Sek. on/ 30 Sek. off (25%)
Conditions for transport and storage	
ambient temperature	-40°C ... +70°C
air humidity relative	30% ... 95%
Conditions for operation	
ambient temperature	+10°C ... +40°C
air humidity relative	30% ... 75%, non condensing

HF Output Power Intensity 50 % and 100 %





CHAPTER 9

Service

Servicing of the instrument, including accessories, comprises preventive and corrective measures for keeping the instrument in good working condition. This the safety inspections which be performed regularly are preventive measures; modifications and repairs fall under the heading of corrective servicing.

The purpose of regular servicing is to keep the instrument, including all reusable accessories, in the satisfactory condition defined by the ratings, and to ensure the operability and safety of the instrument at least until the next servicing date.

Safety Inspections

The regular performace of safety inspections can prevent accidents that can occur as a result of the aging, wear, or malfunction of medicotechnical instruments.

The Ophthalmobipolar E ophthalmosurgical instrument must be inspected at least once a year for compliance with safety regulations.

The following norms are pertinent to the performance of the safety inspections.

- EN 60601-1
- EN 60601-2-2

Safety inspections of the *Ophthalmobipolar E* must include, in particular:

- Visual inspection for defects in the instrument and accessories
- Test of ground lead, in accordance with EN 60601-1
- Test of insulation
- Test of leakage current, in accordance with IEC 601-1
- Performance test
- Test activation of HF output with the footswitch
- HF-output test
- Measurement of current consumption with and without load

In the event that defects are discovered by a safety inspection that could endanger patients, employees, or third persons, the instrument must not be used until such time as these defects have been corrected through expert servicing.

Dies gilt als erfüllt, wenn die konstruktiven und funktionellen Merkmale nicht sicherheitsmindernd verändert wurden.

Modifications and repairs must not diminish the safety of the instrument or

Modifications and Repairs

accessories for patients, the user, or third persons. This conditions is satisfied so long as the structural and functional characteristics of the instrument are not altered so as to diminish its safety.

In view of the special safety requirements in HF surgery, modifications and repairs may be performed only by the manufacturer or by persons expressly authorized by the manufacturer to perform repairs. Should either the instrument or the accessories be modified or repaired incorrectly by an unauthorized person, the manufacturer will not be liable for any resulting damages, and all rights under the warranty are nullified.

If necessary, technical documentation will be provided to authorized persons.

Changing the Mains Safety Fuses

Before changing the fuses remove the mains cable from the Mains Connection Socket (8) !

Remove the caps of the fuses by turning anticlockwise with a screw driver or a coin. Replace the fuses and tighten the caps by turning clockwise.

Connect the mains cable to Socket (8).

WARNUNG 

The mains safety fuses must only be replaced by fuses according to the values pretended on the Name Plate !

Obsolete equipment

Obsolete equipment and accessories can be disposed of wherever electronic waste products are accepted for processing.

CHAPTER 10

Service and Warranty

Service

In order to prevent accidental injuries due to faults occurring in, or to failures of the equipment or of any of its accessories, the equipment and all of its accessories should be regularly checked for proper and safe operation. These checks should be performed exclusively by personnel whose knowledge, training and practical experience qualifies them to perform such checks. A maintenance contract with ERBE is thus advisable after the warranty period.

Warranty

Transport damage

The unit and accessories must be inspected immediately on receipt for deficiencies and transport damage. Claims for compensation can only be enforced when the seller or carrier are notified without delay. A damage report must be compiled.

The warranty period for the unit is 1 year from the date of delivery.

Equipment warranty

Claims under warranty are valid only when the warranty certificate has been properly completed. The warranty covers free repair of the unit provided that the deficiency has been caused by material or manufacturing faults. Other claims, particularly claims for compensation are excluded.

Repairs may only be performed by the equipment's manufacturer or by authorised service agents. Claims under warranty are invalidated if improper modifications or repairs have been undertaken.

Repair work performed under warranty neither extends nor renews the warranty.